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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,703	03/29/2006	Amelie Bochot	BJS-5006-6	1868
23117 7590 02/21/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER EBERHARD, JEFFREY S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 02/21/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/542,703		BOCHOT ET AL.	
	Examiner		Art Unit	
	Jeffrey S. Eberhard, Ph.D.		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because they are indecipherable. They appear to be photocopies of photographs or micrographs, originals of which may be in color. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Color photographs and color drawings are accepted if a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless

already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7-11, 13, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitations preceding the phrase are part of the claimed invention.

Regarding claim 7, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 8, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 9 recites the limitation "one or more substances of interest." There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the substances of interest are water-soluble substances or liposoluble substances." There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "said substance(s) is (are) therapeutically active." There is insufficient antecedent basis for this limitation in the claim.

Claims 11 and 12 provide for the use of the formulation, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 recites the limitation "solid beads with a dense structure." There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "compact phases." There is insufficient antecedent basis for this limitation in the claim.

Claim 16 broadly recites "dried or lyophilized beads, which may or may not be dispersed in an aqueous or non-aqueous liquid or in a gel," and the claim also recites "beads in suspension," which is the narrower statement of the range/limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then

narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (US 6, 103, 271).

The instant claims are drawn to a microencapsulation system comprising an "oily

substance” and a sugar organized into a laminar crystalline structure.

In claims 1, 3, 6 and 7, Applicant recites that the microcapsule is “an essentially organized assembly corresponding to stacks of crystalline structures.” Morrison teaches (column 7, line 52 to column 9, line 27) a microencapsulation system comprising an oily substance (*e.g.*, olive oil, Table I) and a sugar (*e.g.*, gum tragacanth, Table II). To the extent that crystallinity is an inherent physical property of the structure, it has not been established that Applicant’s particles are different than the prior art, which abounds with characterizations of the crystalline properties of lipids and sugars. Morrison teaches particles that appear to meet the compositional limitations of the claims, and the Office does not have the equipment to test whether or not Applicant’s crystal structure differs from the art recognized crystal structure inherent to such compositions. See *In re Fitzgerald*:

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

In claim 4, Applicant recites “The system as claimed in claim 3, characterized in that the oligosaccharides are cyclodextrins. Morrison teaches cyclodextrins at column 10, line 7.

Sugars and lipids are well recognized in the art as having inherent crystalline properties. As such it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use these structures and their inherent crystalline properties for the microencapsulation of lipophilic or labile active ingredients in oral or topical pharmaceutical preparations.

Regarding claims 9-11, Applicant recites that the invention comprises “one or more

substances of interest” that are broadly soluble and “therapeutically active.” Examiner takes this to mean pharmaceutical compositions. Morrison teaches microencapsulation of broadly soluble pharmaceutical compositions at column 12, line 66 to column 13, line 15.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison in view of Imberg (Comprehensive Summaries of Uppsala Dissertations from the Faculty of Pharmacy #304).

Morrison is discussed above, but does not teach packing parameters for lipid crystals in emulsions such as those taught by Applicant. Imberg teaches Jönsson’s continuum of preferred phases and packing parameters (Figure 2), including hexagonal packing in oil-in-water-emulsions. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the ingredients taught by Morrison with the ordered crystal packing scheme taught by Imberg to yield a formulation having the recited crystalline properties.

Claims 5, 8 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison in view of Perrier (US 6,197,757).

Morrison is discussed above, but does not teach the specific use of α -cyclodextrin, nor does it teach the microencapsulation system comprising a dense solid bead formed as a function of the speed, duration or temperature of agitation with a specific particle size of from 0.5 to 3 mm.

Regarding claims 5, 8, 14 and 17, Perrier recites the use of α -cyclodextrin, specifically, "the oligosaccharides can be [α -cyclodextrin]" at column 6, lines 34-41, and further that the particles are of "small dimensions" formed by agitation of the "hydrophobic phase in the aqueous phase," to form an inclusion phase ("oil-in-water emulsion," column 10, lines 25-44). Perrier also teaches the effect of temperature, extent and duration of agitation on particle size of the beads formed (columns 21 and 22, Example 8), indicating that more vigorous agitation will yield smaller particulates. Perrier is specific in characterizing the effect of agitation (*e.g.*, 28 μ m particles at 2000 rpm, 20°C, 1 hr., column 22, first table), while Applicant is less quantitative (*e.g.*, "one micron to several centimeters," "moderate agitation," and 20° to 30°C, instant Specification, page 5, lines 10-14 and 36-39, respectively, claim 17). The adjustment of agitation speed, duration or temperature to yield specific particle size is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the artisan of ordinary skill. Accordingly, this type of modification would have been well within the purview of the person of ordinary skill in the art and no more than an effort to optimize results.

Regarding claims 13, 15 and 16, Morrison teaches the use of "oils" (*e.g.*, olive oil, Table I) in the formulation, which Examiner takes to exemplify a condensed or "compact" phase recited by Applicant in claim 15. In claim 13, Applicant recites "solid beads with a dense structure," while in claim 16, Applicant recites "[the invention] is in the form of beads in suspension, or of dried or lyophilized beads, which may or may not be dispersed in an aqueous or non-aqueous liquid or in a gel." As noted *supra*, this claim fails to set forth the metes and bounds of the invention, so many of the embodiments taught in Morrison or Perrier meet the instant claims limitations. Specifically, Perrier teaches (column 26, lines 45-54) that the

microcapsules are "frozen or lyophilized," and that they have a "thick membrane" which "totally encapsulates" the microparticle. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined Morrison's microencapsulation system comprising an oily substance and a sugar, with the relevant teachings of Perrier regarding the use of α -cyclodextrin and more specific processing parameters to yield a product with the physical properties recited by Applicant.

Regarding claim 18, Morrison and Perrier are discussed above. Based on their combined teachings regarding composition, crystalline properties, agitation speed and particle size, it would have been obvious to a person of ordinary skill in the art at the time the invention was made that like particle size, bead density can be determined by adjusting agitation speed, and is likewise deemed merely a matter of judicious selection and routine optimization which is well within the purview of the artisan of ordinary skill.


Application Status and Examiner Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached from 7:00 am to 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey S. Eberhard, Ph.D.
Patent Examiner
Art Unit 1615


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600